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CENTRAL FAX CENTERJUN 04 2007 Atty Dkt. No.: BIOT-005CON
USSN: 10/684,151**REMARKS**

In view of the following remarks, the Examiner is requested to withdraw the rejection and allow Claims 31-37 and 39-51, the only claims pending and currently under examination in this application.

In the Office Action, Claims 31-37 and 39-51 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Segall et al. (WO 92/18136) in view of Irikura et al. (U.S. Patent No. 3,937,821) and further in view of Altura et al. ("Ca²⁺ coupling in vascular smooth muscle: Mg²⁺ and buffer effects on contractility and membrane Ca²⁺ movements," Canadian Journal of Physiology and Pharmacology, 1982, 60(4) 459-82).

To establish a prima facie case of obviousness, the prior art reference, or references when combined, must teach or suggest all the claim limitations. In re Royka, 180 USPQ 580 (CCPA 1974).

Elements of the claimed invention include: (1) the presence of a dynamic buffering system, and (2) the absence of biological buffer.

In rejecting the claims, the Examiner asserts that Segall teaches all the elements except for: inclusion of a dynamic buffering system and a corresponding lack of a biological buffer. The Examiner reasons that since Altura teaches that there are problems with biological buffers, it would be obvious to remove this type of buffer and replace it with a non-biological buffer. For this element, the Examiner looks to Irikura, citing Irikura's teaching of including sodium lactate in a plasma expander solution.

However, when Irikura teaches the inclusion of sodium lactate, it is not a teaching of a dynamic buffering system but is rather mentioning a component of what is known as a lactated Ringer's (LR) solution.¹ In this type of solution, sodium lactate is used as a source of sodium and to replenish fluid loss and electrolytes. The amounts of sodium

¹ http://www.fda.gov/medwatch/safety/2005/aug_PI/Lactated_Ringers_PI.pdf; accessed May 24, 2007.

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chloride, potassium chloride, and calcium chloride dihydrate added in addition to the sodium lactate give weight to this interpretation, since LR solution is comprised of all of these components, in approximately the same molar equivalents as present in Irikura.

Accordingly Irikura fails to teach or suggest a solution that includes a dynamic buffering system. The mere presence of sodium lactate in Irikura's plasma solution does not mean that it is being used as a dynamic buffer. Rather Irikura teaches sodium lactate's use as in creating an isotonic solution. (col. 6 lines 49-53).

An isotonic solution is not a buffered solution. An isotonic solution is one that has the same salt concentration as the normal cells in the body.² A buffer is comprised of a weak acid and its conjugate base salt, or vice versa, "which by its presence in solution increases the amount of acid or alkali that must be added to cause unit change in pH."³

Absent any teaching of Irikura of a sodium lactate being used as a buffer, one would not modify Segall to include sodium lactate as a dynamic buffer instead of a biological buffer. Segall teaches that a buffer MUST be included in the solution ("The pH of the solution according to the invention is maintained by the use of a physiologically compatible buffer." page 10, lines 26-27).

Because Irikura fails to teach sodium lactate as a component of a buffer, one of skill in the art would not modify Segall to remove the biological buffer and replace it with sodium lactate.

At best, the combined teaching of the references would suggest a composition where a biological buffer is present and sodium lactate is added to it, even in view of Altura's cited teaching. This is because while Altura may disclose problems of biological buffers, there is no teaching or suggestion in Altura of a substitute dynamic buffering

² <http://www.medterms.com/script/main/art.asp?articlekey=4058>; accessed June 1, 2007

³ Van Slyke, J. Biol. Chem. 52, 525 (1922)

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system and Segall teaches that some buffering system is necessary.

Thus, the combined teaching of the references fails to teach or suggest all the elements of the claims, e.g., a solution that has a a dynamic buffer but not a biological buffer.

As such, the Applicants submit that the combined teachings of Segall et al. (WO 92/18136) with those of Irikura et al. and Altura et al. do not teach or suggest all the claim limitations. In view of the foregoing discussion, this rejection may be withdrawn.

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CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BIOT-005CON.

Respectfully submitted,
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Date: June 4, 2007

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